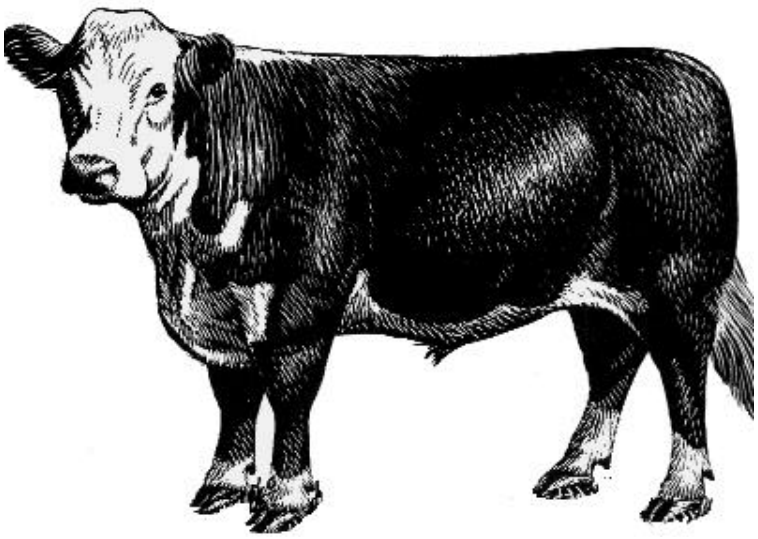
PBIS AND SANITATION



Page intended to be blank

OBJECTIVES

At the end of this session the trainee will be able to accomplish the following objectives.

1. Identify the three sources of authority for performing sanitation inspection.

2. Define the following pre-op sanitation inspection terms:

   a. Area
   b. Unit
   c. Inspection unit

3. From a list of equipment and areas in a red meat plant, select those that are in:

   a. Food contact zones
   b. Non-food contact zone

4. Classify sanitation noncompliance using the most appropriate trend indicator.

5. Define:

   a. U. S. Retained
   b. U. S. Rejected
   c. Repetitive noncompliance

6. Name the official form for documenting pre-operational sanitation noncompliance.

7. Document noncompliance using a Noncompliance Record (NR).

8. Define repetitive noncompliance.

9. List things that should appear in a NR description for repetitive deficiencies.

10. State when, how to, and who notifies the District regarding misrepresentation of plant records.

PART I - AUTHORITY

The Wholesome Meat Act (WMA), Regulations, FSIS Directives provide the authority, requirements, policies, and standards related to sanitation.

FSIS requirements for sanitation are found in the Regulations in Part 416.

PART II - PBIS

The Performance Based Inspection System (PBIS) is the FSIS computer system that schedules procedures FSIS inspectors conduct. Only **off-line** slaughter procedures are documented under PBIS. Which procedures were conducted, the procedure results, and the types of noncompliance identified are all tracked by the automated database.

Off-line vs. Online

PBIS Inspection tasks are conducted by the **off-line slaughter inspector,** who is usually the GS-8, or by someone acting in the absence of the off-line slaughter inspector. For pre-operational sanitation inspection (pre-op) the person acting in the absence of the GS-8 could be a veterinary medical officer (VMO), but most often is a GS-7.

Off-line slaughter activities are commonly called houseman or floor duties, like allied departments, AQL, and boneless meat reinspection.

On-line slaughter activities are those directly related to postmortem inspection procedures. Action is taken against individual carcasses in the areas of contamination, condemnation of parts, and the retaining of carcasses for final disposition.

Some procedures, like presentation and sanitary dressing, can be performed as either part of the on-line postmortem inspection, or, under certain conditions, as an off-line activity. For example, on-line inspectors assure that carcasses are correctly presented. When a single carcass is presented improperly, e.g. kidneys not exposed for inspection, the inspector takes appropriate action. However, if carcasses are repeatedly improperly, presentation process control is questionable. The on-line inspector should notify the off-line slaughter inspector.

Determining whether presentation is in control is the duty of the off-line slaughter inspector. Generally speaking, the on-line inspector takes action on individual carcasses; whereas, the off-line inspector takes action on both the process and the affected product.

In a small, one inspector plant, the IIC is the person responsible for both **on-line** postmortem inspection and **off-line** PBIS duties. He or she must determine when process control becomes questionable. Then, acting in an **off-line** capacity, assess the overall situation and determine whether the process is in compliance.

Inspection System Procedure Guide (ISP)

The Inspection Procedure Guide (ISP) lists and describes FSIS procedures. The following excerpt from the ISP is an example procedure.

01A01	Written SSOPs describe procedures the establishment conducts daily to prevent direct contamination or adulteration of products. Pre-operational procedures are identified. Pre-operational procedures address the cleaning of food contact surfaces of facilities, equipment, and utensils. The frequency of SSOP is specified in each procedure. The employee(s) responsible for implementing and maintaining the procedures are identified. Identified records, on a daily……..	Part 416 FSIS Dirs. 5000.1 Part 3, Par. II	As appropriate, review Sanitation SOPs and recordkeeping. Make determination about compliance with regulatory requirements. Document failure(s) to comply with regulatory requirements on NR and (when appropriate) take other action consistent with applicable directive(s).

Four columns in the ISP give information about each procedure. Reading from left to right:

The first column contains the ISP code, which is unique to that procedure.

The second column is the Compliance Standards column. It identifies plant responsibilities and briefly summarizes FSIS standards.

The third column lists references for in-depth information about the Agency's standards for the procedure.

The fourth column tells the inspector how to conduct the procedure.

Noncompliance Record (NR)

An establishment's failure to comply with a regulatory requirement is called **noncompliance.** A process, product, facility, equipment, or plant employee's work habits can be the cause of noncompliance. Inspectors must consider what is **known for a fact** and what **can be reasonably assumed** when deciding whether or not a noncompliance exists.

When there is noncompliance, complete a Noncompliance Record (NR) FSIS Form5400-4. A NR serves as official documentation, notification, and status of inspection findings to plant management. It is a legal record, so it is extremely important to complete it accurately.

Detailed instructions for completing a NR begin on page **17.**

Procedure Schedule (PS)

Each week the IIC receives a package of documents that list procedures to be conducted by off-line inspectors each shift every day. The daily list is called the **Procedure Schedule (PS).** GS-7 slaughter inspectors and VMOs who perform HACCP procedures will record their inspection results on a blank PS. Unscheduled procedures also are recorded on a blank PS.

Here's how to complete the PS.

One of three following inspection results must be circled when any procedure is conducted.:

- Performed (with compliance)
- Trend Indicator (with noncompliance)
- Not performed

Performed with compliance

If the procedure indicates **compliance** with regulatory requirements, circle "**a" Performed** on the PS.

Trend Indicator with noncompliance

If the results of a procedure indicate **noncompliance,** circle the letter and name of the most appropriate **Trend indicator.**

For example, if an inspector observed that an establishment employee did not initial or date an entry on an SSOP record (recordkeeping noncompliance), "**e" recordkeeping** would be circled.

Procedure not Performed

If the scheduled procedure is not performed, circle "**b" not performed** on the schedule.

An example of a completed PS is on page **9**.

For unscheduled sanitation procedures, results may be recorded on the bottom of the PS if there is room, or on a blank PS.

Here's how to fill out a blank PS.

1. Fill in the establishment/shift

2. Fill in the visited date.

3. Write the procedure code in the procedure column.

4. Write the letter for the appropriate result code in the Result column. (Letters for results are listed on the bottom half of the blank PS.)

An example of a completed blank PS is on page **10**.

PART III. SANITATION STANDARD OPERATING PROCEDURES (SSOP)

To control sanitation hazards that cause direct product contamination, every federally inspected plant is required by FSIS Regulation 416 to develop and maintain an SSOP. It is plant management's responsibility to adhere to the SSOP to ensure product is not adulterated or contaminated. The FSIS inspector's principal role in the plant is to **verify** the adequacy of plant sanitation procedures. FSIS does not approve the SSOP or SSOP revisions. SSOP noncompliance is documented on a Noncompliance record (NR).

Plant Responsibilities

Each establishment develops and keeps its SSOP up-to-date. The Final Rule requires:

- All inspected establishments develop, implement and maintain written SSOPs.
- SSOPs specify routine sanitation procedures the establishment conducts before (pre-operational) and during operations (operational) to prevent direct contamination or adulteration of products. SSOPs must also include procedures to prevent conditions that cause direct product contamination or adulteration.
- The pre-operational sanitation procedures must address the cleaning of food contact surfaces of facilities, equipment, and utensils.
- The SSOP must identify the person(s) responsible for monitoring sanitation activities, evaluating SSOP effectiveness, and initiating corrective actions.

According to Regulations, corrective actions are not complete until the following steps are accomplished:

1) appropriate disposition of contaminated or adulterated product.
2) restoration of sanitary conditions
3) prevention of the recurrence of direct product contamination, including appropriate reevaluation and modification of the SSOP when necessary

- Daily records must be kept. They must show when procedures listed in the SSOP were done and when corrective actions were taken.

  Regulatory requirements for company SSOP records are as follow:

  - Records must be generated daily. The establishment has 24 hours to complete SSOP records.
  - They must document the intended activity, condition, or result
  - They must be initialed and dated by the responsible plant official.
  - They must be legible.
  - FSIS must be given access to all establishment sanitation records.
  - For the first 48 hours, SSOP records should be kept in the establishment. For the nest six months, the company may keep their records either in the establishment or elsewhere, provided they can be produced within 24 hours of a request from inspection personnel.

  NOTE: SSOP records are plant property and are not subject to the Freedom of Information Act (FOIA). FSIS inspectors must not copy them, unless instructed to do so by the District Office. Sanitation records are **not** kept in the FSIS files.

- The individual with overall authority on-site (or a higher level official) must **sign** and **date** the SSOP

Specific corrective actions or preventive measures are not required to be included in the SSOP, (but they **MUST** be addressed in blocks 12 and 13 of a NR).

Noncompliance Determination Guide (NDG)

The Noncompliance Determination Guide (NDG) sorts types of noncompliance into groups called **trend indicators.** Using the NDG, Inspectors can determine which trend indicator best describes the noncompliance. An abbreviated version of the NDG is on the back of the NR.

The table below shows the trend indicators used to document noncompliance throughout a plant.

NONCOMPLIANCE CLASSIFICATION INDICATORS		
Plant Process	A. ☐ SSOP B. ☐ HACCP	☐ Monitoring ☐ Corrective Action ☐ Recordkeeping ☐ Implementation ☐ Monitoring ☐Corrective Action ☐ Recordkeeping ☐ Plant Verification
C. ☐ Product		☐ Economic ☐ Misbranding ☐ Protocol
D. ☐ Facility		☐ Lighting ☐ Structural ☐ Outside Premises ☐ Product Based
E. ☐ E. coli		☐ Other

Noncompliance found during pre-operational and operational sanitation will be categorized on line A (SSOP) of the above chart or, in some cases, on line D (Facility) of the above chart.

Let's look more closely at these SSOP trend indicators and learn when each one should be used.

SSOP – Monitoring

Monitoring noncompliance occurs when the plant:

- fails to monitor its pre-operational and operational sanitation procedures daily.
- monitors sanitation but overlooks noncompliance
- fails to monitor operational sanitation at the frequency stated in SSOP

SSOP – Corrective Action

The corrective action trend indicator is used when:

- the plant SSOP fails to prevent contamination or adulteration of product.
- the plant fails to take all of the corrective actions required by section 416.15 of the regulations which must include the following:
    - appropriate disposition of product(s)
    - restoration of sanitary conditions
    - prevention of recurrence of direct product contamination.

For example, plant personnel fail to clean and sanitize equipment they found during pre-op prior to using it.

- corrective actions or further planned actions previously proposed by the plant were not implemented or failed to prevent recurrence of direct product contamination of products.

SSOP – Recordkeeping

The recordkeeping trend indicator is used when

- SSOP records are not initialed and dated
- SSOP records are not maintained daily
- SSOP records are not kept for the required amount of time
- the plant fails to record the results of a monitoring check that was conducted
- records of corrective actions taken are not maintained

(If the plant is not maintaining any records at all, it would be documented under procedure code 01A01 as basic noncompliance.)

SSOP – Implementation

This trend indicator applies when two or more types of noncompliance are found while conducting one procedure. For example, an inspector who finds recordkeeping noncompliance and corrective action noncompliance while conducting pre-operational sanitation inspection would mark **implementation.** Another example is if two inspectors conducted pre-operational sanitation inspection and one found recordkeeping noncompliance while the other found monitoring noncompliance. The most appropriate trend indicator would be implementation.

Facility – Product Based

The product based trend indicator is used when a sanitation noncompliance identified on pre-op would not result in direct product contamination or is not an insanitary condition covered by the SSOP. For example, it is used when product residue, such as fat, or meat scraps, is found on the leg of a head boning. The leg of the table is not a direct product contact surface. There is no threat of direct product contamination; therefore this noncompliance does not come under the SSOP. Document under the 06D01 procedure code marking the product based trend indicator.

FSIS Responsibilities

FSIS is responsible for verifying that plant management implements the SSOP as it is written.

The IIC is responsible for determining when there is an inadequate SSOP system. Inspectors should discuss their concerns with their supervisor when they suspect an inadequate system.

Inadequate SSOP System

Three situations that can cause an inadequate SSOP system are:

1. **Failure** to meet the **basic regulatory requirements**

   If the establishment does not implement some or all of its SSOP, it does not meet the **basic regulatory requirements.** For example, if an establishment does not maintain **any** records or if it does not monitor the SSOP **at all**, then it does not meet the **basic regulatory requirements,** and Inspection cannot determine whether or not the establishment produced adulterated product. FSIS considers this an inadequate system.

2. **Shipping contaminated or adulterated product produced under the SSOP**

   There is an inadequate system anytime the SSOP does not keep adulterated or contaminated product from being produced and leaving the plant.

   If the IIC determines there is an inadequate SSOP system for either of the first two reasons, he or she should follow these enforcement actions.

- Withhold inspection and notify the establishment.
- Write a NR and give plant management a copy.
- Notify the District Office of actions taken. The District Manager will give instructions for further enforcement action.

3. **Repetitive SSOP failures**

Two things must happen before an SSOP system is considered inadequate because of repetitive failures.

- First, adulterated or contaminated product must be produced. (Note: Although produced, the adulterated or contaminated product is **not** shipped.) Each time adulterated or contaminated product is produced because the SSOP did not prevent it, the resulting noncompliance is an SSOP failure.

- Second, adulterated or contaminated product must be produced repeatedly, i.e., multiple cases of SSOP failure. Careful analysis must be made before determining that an inadequate SSOP system exists. Previous NRs and PDRs must link production of contaminated or adulterated product to the same cause. Documentation is important! Record the numbers, dates, and unsuccessful preventive measures from previous NRs and PDRs in the description block of each new NR to make the links obvious.

- SSOP repetitive failures can occur because the SSOP is not:

    1) adequate to prevent contamination or adulteration as written.

    2) executed properly by plant personnel.

If the IIC determines there is an inadequate SSOP system because of repetitive failures, he or she should take the following enforcement action.

- Tag affected products and/or portions of the facility that do not meet sanitary requirements. Tags should remain in place until the establishment completes all 3 required components of corrective actions.

- Advise plant management by giving them a copy of the NR.

- Notify the District Office that he/she thinks there is an inadequate SSOP system. The IIC must provide the District Office with specific nonconcompliance information,

including NR numbers.

- The District Manager discusses the case with the IIC and gives instructions regarding enforcement action to take in the plant. If the District agrees there is an inadequate SSOP system, a Notice of Intended Enforcement Action is issued to the company. The letter gives the company 3 days from receipt of the letter to make corrective actions and propose preventive measures or inspection will be suspended at the plant.

- The District Manager reviews the plant's response and determines whether or not to suspend inspection.

Records Misrepresentation

Familiarity with a plant's procedures and compliance history will help separate honest errors from deliberate record misrepresentation. When deliberate misrepresentation of records is suspected, do **not** discuss the situation with a plant employee. Instead, notify the IIC. Document the findings in a memorandum to the files—**not on a NR.** The IIC should use a **secure** phone (off-premises, if necessary) to call the District Office. FSIS does not consider the telephone in the Government office and cellular phones to be secure. The District Manager, or designee, will provide instructions for further action.

If the IIC is not available, the inspector should use a secure phone to notify the District Office and follow the District Manager's instructions.

NONCOMPLIANCE RECORD COMPLETION FOR SANITATION INSPECTION

*(An example of a completed NR is on page **22**.)*

The plant may respond to an NR in writing or verbally. Verbal responses can be recorded on the NR by an inspector.

Type of Noncompliance

Check the Food safety box in the top right hand corner if the noncompliance involves direct product contamination/adulteration or the threat of product contamination/adulteration, e.g., food residues found on an the blade of a carcass splitting saw during pre-op inspection.

Check the Other Consumer Protection Box if noncompliance does not involve direct product contamination/adulteration or the threat of direct product contamination/adulteration, (e.g.,food residues found on the floor beneath the head boning table).

The following table lists the activity numbers in the Inspection Procedure Guide (ISP) classified as "Food Safety" or "Other Consumer Protection."

Food Safety	**Other Consumer Protection**
Any 01-SSOP	Any 04-Economic/Wholesomeness
Any 03-HACCP	05B01-Economic Sampling Scheduled
05A01-Micro. sampling for E.coli	Any 06-Other Requirements
05A02-Micro. sampling for E.coli	
05A03-Micro. sampling for Salmonella	
05B02-Directed sampling	
05C01-Residue	

Note: The block "attachment,"top right, of the NR Continuation Sheet, FSIS Form 5400-4a, is checked only if an inspection employee is continuing a description from Block 10 of an NR, FSIS Form 5400-4.

Blocks 1, Date

Record the date the procedure was performed. Enter the name of the month, e.g., March 21, 1999, Mar. 21,1999; or a numeric date, e.g., 3/21/99, or 3-21-99.

Block 2, Record No.

Number NRs sequentially starting with the number "1" followed by a dash and the year. e.g.,1-99, 2-99, etc.

Block 3. Establishment No.

Record the eight digit establishment number, e.g., M-38, should be recorded as 00038--M. If there is more than one shift, include the shift number by adding a forward slash and the shift number at the end of the establishment number, 00038--M/1.

Block 4: To (Name and Title).

Enter the name and title of the responsible establishment official. For an SSOP noncompliance, enter the name of the person who signed the SSOP.

Block 5: Personnel Notified.

Enter the name(s) of the establishment management personnel notified about the noncompliance.

Block 6: Relevant Regulations.

Cite the specific regulation(s) with which the establishment failed to comply. For example, if the establishment fails to take corrective action in response to direct product contamination, Reg. 416.15 would be entered. Do not enter every regulation listed in the reference column of the ISP unless they all apply to the noncompliance.

Block 7: Relevant Section/Page of Establishment Procedure/Plan.

When noncompliance represents a failure to comply with the written provision of a plant procedure or plan, enter the section or page of the establishment's procedure or plan. For example, if the establishment fails to take corrective action in response to direct product contamination, the appropriate section or page of the SSOP that addresses corrective actions is entered on the left side of the block. Place an "X" in the box on the right side of the block in the SOP box.

Block 8: ISP Code.

Enter the procedure code.

Block 9: Noncompliance Classification Indicators.

Mark the trend indicator that best describes the noncompliance.

Block 10: Description of the Noncompliance.

Describe the exact problem, location and effect on product in clear, concise detail. If more space is needed to describe the noncompliance use an NR Continuation Sheet. Write "See Attachment" at the end of the description to alert the reader that there is more information on a continuation sheet.

The NR **continuation sheet** may be used in two ways.

1) It is used when multiple inspectors conduct pre-operational sanitation inspection.
2) It may be used when extra space is needed to complete a description of noncompliance.

Check the block “attachment” in the top right corner of the Continuation Sheet. Copy the NR number onto the continuation sheet. It is not necessary to complete the remainder of blocks 1 through 8 from the NR onto the continuation Sheet.

Block 11: Signature of Inspection Program Employee.

The inspector signs the NR after blocks 1 through 10 have been completed.

Blocks 12 and 13: Plant Management Response.

Block 12, **Immediate Action (s)** taken must ensure proper disposition of contaminated products and restore sanitary conditions. Plant management should document what was done to correct the noncompliance, that is, to bring itself back into compliance.

Block 13, **Further planned action(s)** must propose ways to prevent recurrence of the noncompliance. At times the plant might reevaluate and modify its SSOP to prevent contamination.

Block 14: Signature of Plant Management Official.

The plant official designated to respond to the NR signs his/her name (voluntary) after the immediate action or further planned action has taken place. If the designated plant management official refuses to sign the NR, a statement such as “plant management refused to sign.” Should be written by the inspector in placed of the signature.

Block 15: Date

The designated official records the date he/she signed the NR.

Block 16 and 17: Verification signature of Inspection Program Employee and Date

After reviewing plant management’s response in blocks12-15, the inspector verifies that acceptable immediate and further planned actions were taken. If actions are to be taken by plant management at a later time, the inspector will hold the original and first copy of the NR in the Open File for review and verification by the agreed time.

The inspector who verifies that immediate and further planned actions were

taken, signs this block and records the date.

Distribution of NRs after Completion of Blocks 16 and 17

The original is filed in the NR Closed File and the first copy is given to plant management.

PBIS AND SSOP WORKSHOPS

Trend Indicators

Match the examples of noncompliance in the left column with the most appropriate trend indicator from the right column.

____SSOP records are not signed

____Plant personnel did not conduct pre-op as required by SSOP

____SSOP records not documented for 3 days this week

____SSOP records indicate that noncompliance found on pre-op inspection was cleaned; preventive actions not addressed

____Inspector found fat scraps and blood on floor at head inspection station

____Inspector found fat build-up on split saw after plant had completed pre-op monitoring and corrective actions

____QA manager found blood and fat residue on brisket saw on pre-op; not cleaned prior to start

____SSOP records are kept by plant for 4 months

____SSOP records for 2/2/99 are not completed after 24 hours

____Slaughter pre-op inspector found undated SSOP record for 2/3/99: processing pre-op inspector found beef fat on grinder blades.

A. SSOP- Monitoring

B. SSOP- Corrective Action

C. SSOP- Recordkeeping

D.SSOP- Implementation

E. Facility- Product-Based

Read each scenario. Determine if noncompliance exists. Select the most appropriate trend indicator.

SCENARIO

Inspector Charles George performed procedure 01B02 (review and observation of pre-operational sanitation inspection) at M-38 on March 3, 1999. The establishment's Sanitation SOP, states that all equipment will be cleaned and sanitized prior to production and that monitoring activities will be performed daily by the sanitation manager during pre-op sanitation inspection. Charles observed the following:

- Plant pre-op had been completed but operations had not yet begun.
- Several pieces of dried fat and meat tissues (1/4 inch or greater in diameter) were observed on the blade of the band saw. The blade contacts exposed carcass parts.
- Establishment's Sanitation Form E-1, dated 3/3/99, indicated that the sanitation manager inspected all equipment and the band saw was unacceptable. Operations could not begin until the saw was cleaned, sanitized, reinspected and found to be acceptable.

Charles returned to the USDA inspection office. On his way to schedule a meeting with management he noticed that operations had just begun. Product had not reached the band saw.

He walked by the band saw and observed the same pieces of dried fat and meat on the blade of the saw.

9. NONCOMPLIANCE CLASSIFICATION INDICATORS					
Plant Process	A. ☐ SSOP	☐ Monitoring	☐ Corrective Action	☐ Recordkeeping	☐ Implementation
	B. ☐ HACCP	☐ Monitoring	☐ Corrective Action	☐ Recordkeeping	☐ Plant Verification
C. ☐ Product		☐ Economic	☐ Misbranding	☐ Protocol	
D. ☐ Facility		☐ Lighting	☐ Structural	☐ Outside Premises	☐ Product Based

E. ☐ E. COLI	☐Other

SCENARIO

On February 11, 1999, Inspector Carolyn Alexander performed procedure 01B02 (review and observation of pre-operational sanitation inspection) at M-38, Bargain Packing Company. The Establishment's Sanitation SOP states that all equipment will be cleaned and sanitized prior to production and that monitoring activities will be performed daily by the sanitation manager during pre-op sanitation inspection. She observes the following:

- Plant pre-op had been completed but operations had not yet begun.
- several dried pieces of fat and meat scraps were observed on the legs of the head boning table.
- Sanitation Form E-1, dated February 11, 1999, indicated that the sanitation manager had monitored pre-operational sanitation at 6:00 a.m. and found it acceptable.

9. NONCOMPLIANCE CLASSIFICATION INDICATORS					
Plant Process	A. ☐ SSOP	☐ Monitoring	☐ Corrective Action	☐ Recordkeeping	☐ Implementation
	B. ☐ HACCP	☐ Monitoring	☐ Corrective Action	☐ Recordkeeping	☐ Plant Verification
C. ☐ Product		☐ Economic	☐ Misbranding	☐ Protocol	
D. ☐ Facility		☐ Lighting	☐ Structural	☐ Outside Premises	☐ Product Based
E. ☐ E. COLI		☐ Other			

Noncompliance Report (NR)

Read the following scenario. If there is noncompliance, complete an **NR** using the following information:

- Jonathan Perez, Plant Manager, receives NRs.
- Pre-operational sanitation is addressed on on page 5 of the SSOP.
  It states that all equipment will be cleaned and sanitized prior to operation. The QC supervisor performs pre-op monitoring daily.
- Pre-op is conducted on the first shift.
- Date is 1/31/99
- The next NR number 18.

SCENARIO

Inspector Cheryl Taylor performed the review and observation component of procedure (01B02) in Establishment M-38 at 6:05 A.M. She observed John Pardini, QC supervisor, perform pre-op sanitation inspection monitoring. John did not inspect the contact surfaces of the carcass splitting saw but documented on the Daily Sanitation Record that the slaughter area had been inspected and found acceptable. Cheryl classified this information as a “Monitoring” trend indicator.

Inspector Claudeen Jones performed the review and observation component of procedure (01B02) in the fabrication area of the plant at 6:35 A.M. Dorothy King, the second processing foreman, informed Claudeen that pre-operational sanitation inspection was completed at 6:30 A.M. She also stated that all contaminated areas identified had been documented and that all corrective actions had been completed and recorded. During her organoleptic inspection, Claudeen found an accumulation of fat (3" x 6") on top of the boning table on line number 2, and dried meat (4" x 3½") on the conveyor belt of boning line number 4. When she looked at the establishment ‘s sanitation report, she noted that the foreman documented the same findings.. The records also showed that corrections were completed.

Claudine withheld inspection from the area with U.S. Reject tag #56789231. She documented the noncompliance on an NR Continuation Sheet and documented that the appropriate trend indicator would be “corrective action”.

U.S. DEPARTMENT OF AGRICULTURE FOOD SAFETY AND INSPECTION SERVICE **NONCOMPLIANCE RECORD**	Type of Noncompliance ☐ Food Safety ☐ Other Consumer Protection		

1. Date	2. Record No.	3. Establishment no.

4. To (*Name and Title*	5. Personnel Notified

6. Relevant Regulation(s)

7. Relevant Section/Page of Establishment Procedure/Plan ≡	HACCP	SOP	OTHER

8. ISP Code

9. NONCOMPLIANCE CLASSIFICATION INDICATORS

Plant Process	A. ☐ SSOP	☐Monitoring	☐Corrective Action	☐ Recordkeeping	☐Implementation
	B. ☐ HACCP	☐Monitoring	☐Corrective Action	☐ Recordkeeping	☐Plant Verification
C. ☐ Product		☐Economic	☐Misbranding	☐ Protocol	
D. ☐ Facility		☐Lighting	☐ Structural	☐Outside Premises	☐Product Based
E. ☐ E. COLI		☐Other			

10. Description of Noncompliance:

11. Signature of Inspection Program Employee

You are hereby advised of your right to appeal this decision as delineated by 306.5 and/or 381.35 of 9 CFR.

12. Plant Management Response: (Immediate action(s)):

13. Plant Management Response (further planned action(s)):

This document serves as written notification of your failure to comply with regulatory requirement(s) which could result in additional regulatory and administrative action.

14. Signature of Plant Management	15. Date
16. Verification Signature of Inspection Program Employee	17. Date

FSIS FORM 5400-4 (7/98)

ORIGINAL & 1 copy - Establishment
1 copy - Inspector
☐ Attachment

U.S. DEPARTMENT OF AGRICULTURE FOOD SAFETY AND INSPECTION SERVICE **NONCOMPLIANCE RECORD** **CONTINUATION SHEET**	Type of Noncompliance ☐ Food Safety ☐ Other Consumer Protection	.	

1. Date	2. Record No	3. Establishment No.

4. To (*Name and Title*)	5. Personnel Notified

6. Relevant Regulation(s)

7. Relevant Section/Page of Establishment Procedure/Plan ≡ | HACCP | SOP | OTHER

8. ISP Code	9. Noncompliance Indicator

10. Signature of Inspection Program Employee	11. Date

FSIS FORM 5400-4a (7/98)

ORIGINAL & 1 copy- Establishment
1 copy-Inspector

Procedure Schedule

Use the following information to complete the PS. (The directions for completing a PS are on page 7.

SCENARIO

- Establishment M-38, Shift 1
- Operating hours from 0630 – 1500
- Visited date:2/2/99
- You were assigned the pre-operational sanitation procedure (01B02)
- The results of your inspection indicated that the establishment was acceptable for operation.

Misrepresentation of Records

Read the scenario. Answer the question.

Inspector I.M. Great performed records review and organoleptic pre-op inspection (procedure 01B02) at M-38, Joepa Packing Company, on 2/23/99. She made the following observations.

- The plant had completed Pre-Op. Operations had not begun.
- The grinder plate and blade had dried meat and fat stuck their surfaces.
- Inspector Great reviewed the plant's records dated 2/23/99. She noted that Edward Jones, the QC technician found the grinder unacceptable at 6:00 A.M. The documented corrective action said the grinder was disassembled, cleaned, sanitized, and reassembled. It was reinspected and found acceptable by Mr. Jones at 6:20 A.M. Mr. Jones' signature was at the bottom of the page.
- When Inspector Great tried to find Mr. Jones she was informed that he left at 4:15 A.M. because of a family emergency.

Question:

If you were Inspector Great, would you suspect deliberate records misrepresentation? What would you do?

Sanitation SOPs

Answer the following:

1. Name five (5) requirements for plant sanitation records.

2. Name four (4) SSOP regulatory requirements.

3. Do specific corrective actions and preventive measures have to be included in the SSOP?

4. Name the document to record noncompliance.

5. List three (3) things that cause an SSOP inadequate system.

6. Who is responsible for determining when an inadequate SSOP system exists?

7. List items that should be included in the description of an NR when documenting repetitive noncompliance.

8. What is the difference between an SSOP failure and an SSOP inadequate system?

9. List the enforcement actions taken by the IIC and District Manager when adulterated product produced under the SSOP is shipped.

10. List the enforcement actions taken by the IIC and District Manager when there is an inadequate SSOP system based on repetitive failures.

Word Find

Step 1. Fill in the blanks using the text in the module.

The Wholesome Meat Act, _____, and FSIS Directives provide the authority for an inspector to conduct pre-operational and operational sanitation procedures.

_____slaughter activities are those commonly called floor duties, like net weights carcass AQL, and boneless meat reinspection.

_____slaughter inspection activities are related to postmortem inspection procedures.

ISP….

The first column contains the _____, which is unique to that procedure.

The second column is the _____ column.

The third column lists _____ for in-depth information about the Agency's standards for the procedure.

Inspectors must consider what is _____ and what can be reasonably assumed when deciding whether or not noncompliance exists.

When there is noncompliance, complete a _____(NR), FSIS
Form 5400-4.

Each week the IIC receives a package of documents that list the procedures to be conducted by off-line inspectors on each shift every day. The daily list is called the _____
(PS).

If the results of the procedure indicate _____, circle the letter and name of the most appropriate trend indicator.

If the scheduled procedure is not performed, circle b)_____
on the schedule.

FSIS does not approve the _____ or SSOP revisions.

All inspected establishments _____, _____, and
_____ written SSOPs.

According to the Regulations, corrective actions are not complete until the following steps are accomplished.

1) Appropriate _____ of contaminated products

2) _____ of sanitary conditions.

3) _____ of recurrence of direct product contamination,

including appropriate reevaluation and modification of the SSOP when necessary.

Sanitation records must:

- be generated daily
- be maintained at the plant for at least 48 hours after completion
- document the intended activity, condition, or result

- be _____ and _____ by the responsible plant official
- be _____
- document _____ taken or required to be taken.

_____ noncompliance occurs when the plant

- fails to monitor their pre-operational or operational sanitation procedures daily
- monitors sanitation but overlooks noncompliance
- fails to monitor operational sanitation at the frequency stated in SSOP

The _____ trend indicator is used when

- SSOP records are not initialed
- SSOP records are not maintained daily
- SSOP records are not kept for the required amount of time
- The plant fails to record the results of a monitoring check that was conducted
- Records of corrective actions taken are not maintained

For example, an inspector who finds recordkeeping noncompliance and corrective action noncompliance while conducting pre-operational sanitation inspection would mark _____.

The _____ trend indicator is used when noncompliance identified on pre-op does not result in direct product contamination or an insanitary condition covered by the SSOP.

_____ noncompliance has the same root cause and recurs because of plant management's negligence, ineffectiveness, or incomplete execution of the SSOP.

The IIC is responsible for determining when there is an _____system.

Familiarity with a plant's procedures and compliance history will help separate honest errors from deliberate records _____.

PART IV – PRE-OPERATIONAL SANITATION – 01B01 and 01B02

This section describes the method used by inspectors to conduct procedure 01B01 (recordkeeping) to verify the adequacy of the plant's SSOP, and procedure 01B02 (review and evaluation, plus review of sanitation records).

Pre—Operational Sanitation Definitions

Acceptable Unit: A unit that meets the sanitation standards defined by the IIC

Area: A major portion of a slaughter plant (e. g., picking area, eviscerating area, major equipment groupings like the chillers, etc.) *Note:* One inspector's pre-op assignment can cover up to five areas.

Inspection Unit (IU): A unit selected for inspection. (See unit)

Pre-operational Sanitation Inspection (Pre-op): The inspection of premises, facilities, equipment, and utensils prior to the start of production to determine the acceptability of the clean-up program

Random sample: A group of IUs, each of which has an equal chance of selection

Unit: One of the sequentially numbered, three-dimensional sections within an area that can be inspected in one-minute. (Noncompliance recording time is not included in the one-minute inspection time.)

Note: Portable equipment that is displaced during cleaning will not always be located within the same unit at the time of pre-op inspection. Such equipment should be inspected within the boundaries of the unit in which it is located.

Time Allotted

The pre-op start time is determined by the IIC based on the number of Inspection Units selected, establishment pre-op record availability, and the amount of time the establishment needs to perform lockout/tagout on the selected equipment.

Instructions for Inspectors

All inspection personnel responsible for conducting pre-operational sanitation inspection perform one pre-op procedure each day of operation.
A properly equipped inspector conducting organoleptic pre-op sanitation inspection needs:

- a good flashlight
- a pen or pencil
- U.S. Rejected/U. S. Retained tags, and some means of affixing these tags (such as tape, string, or rubber bands)
- a clipboard
- FSIS Form 5400-4 (NR) or FSIS Form 5400-4a (NR Continuation Sheet)
- areas map from the pre-op plan (The pre-op route should be planned--not haphazard.)

An inspector who is **not properly trained** in lockout/tagout safety **will not,** under any circumstances, inspect a machine or piece of equipment that must be locked out.

Real product protection starts with a good pre-operative clean-up. Each day inspectors must conduct a pre-operational sanitation verification – either a **recordkeeping procedure** (01B01) or a **review and observation procedure** (01B02) – to determine the adequacy and effectiveness of the establishment's Sanitation SOP.

Records Review Procedure (01B01)

Recordkeeping procedures review the plant's daily documentation of its SanitationSOP and any required corrective actions. Inspectors perform this procedure to verify that:

- SSOP procedures are being followed by plant personnel before and during operations

- Monitoring activities are conducted at the specified frequency

- All 3 requirements for corrective actions are implemented and documented as required

- Establishment employees specified in the SSOP initial and date records. When SSOP records are kept on a computer, the establishment must implement controls to ensure data integrity.

The inspector should determine if there is any evidence of misrepresentation or falsification of SSOP records.

Review and Observation Procedure 01B02

The review and observation procedure has three elements.

- direct observation of the plant's implementation and monitoring of sanitation procedures and corrective actions

- organoleptic examination of a random sample of facilities, utensils, and equipment to assess sanitary conditions

- a comparison of inspection findings with plant records for the day

Review and observation may be conducted using some or all of the parts. For example, the inspector might choose to observe plant personnel conducting pre-op or to conduct pre-op inspection and compare the findings to plant records.

In another example, an inspector might conduct organoleptic inspection at the same time plant personnel are conducting pre-op monitoring. If pre-op is done at the same time, FSIS should give the establishment an opportunity to execute its SSOP. For example, M-38 specified in its SSOP that QC will monitor pre-operational sanitation from 6:00 A.M. until 6:30 A.M. using a random sample. FSIS also performs the pre-op review and observation procedure from 6:00 A.M. until 6:30 A.M. If an inspector finds noncompliance in Area I at 6:35 A.M, and establishment personnel are still monitoring area I, the inspector should let the plant complete pre-op in Area I. Once the plant has

completed pre-op, the inspector should reject any unit in which noncompliance was overlooked.

Apply FSIS Form 6502-1 (U.S. Rejected/U.S.Retained tag) to rejected units.

FSIS Form 6502-1 is used to reject a department, equipment, or to retain carcasses or parts.

U.S. Rejected means the *equipment or facility* cannot be used in the processing of any meat product until it is found by an inspector to be sanitary and otherwise eligible for use.

U.S. Retained means the *carcass, viscera, carcass part, or other product* is held by an inspector for further determination as to its disposal.

U.S. Rejected/U.S. Retained tags are serially numbered and have corresponding numbered stubs. Use the tags correctly to avoid the problems associated with lost tags.

- The tag must be completed on both sides.
- It must be securely affixed.
- The appropriate plant official must be notified.
- The tag stub must be detached and held by the inspection team.
- Tag use should receive proper follow-up, that is, once the deficiency is corrected, promptly remove the tag.

Since plant management is accountable for lost tags, plant employees must be trained to handle tags properly.

GENERAL RULES FOR PRE-OP SANITATION INSPECTION

- Surfaces in the **food contact zone** must be clean prior to operations. Clean means free of foreign material such as fat, blood, hair, rust, grease, and cleaning chemicals. Other areas within the food contact zone are those located directly over exposed product. When overhead areas become s source of dripping condensation, peeling paint, or scaling rust, operations must not begin until the situation is corrected. Remember that sanitation problems within the food contact zone

constitute **noncompliance** with the SSOP and require immediate regulatory control action if the plant fails to correct the source of the contamination.

- If noncompliance is found, document it on a NR, and mark the most appropriate trend indicator.

- When noncompliance is found, the plant must complete all three parts of corrective action before the tag is removed. The three parts of corrective action are:

    - Proper disposition of product
    - Restoration of sanitary conditions
    - Proposing acceptable preventive measures

- If an inspector "stumbles on" noncompliance in a unit that was not included in the initial IU sample, the noncompliance should be handled the same as a sample unit, i.e., take regulatory control action and document it.

- When noncompliance is found in **non-food contact zones** of the plant, do not use an SSOP trend indicator. The non-food contact zones do not touch exposed product. Noncompliance in these areas does not constitute a **direct threat** to product; therefore, does not go under the SSOP.

    - If only non-food contact zone noncompliance is found during pre-op, cite procedure 06D01 on the NR, and mark the *Facility – Product Based* trend indicator. Document 06D01 as an unscheduled procedure on the bottom of the PS if there room, or on a blank PS.

    - Projects involving **long-term** or continuing facility improvements are coded under 06D01 and marked under the most appropriate indicator in the Facility category. For example, the **Facility–Structural** trend indicator would be most appropriate to document noncompliance like peeling paint located on a wall away from product. Record this noncompliance as an unscheduled procedure.

    - When noncompliance is found in **both** a food contact zone and a nonfood contact zone during pre-op sanitation inspection, record all descriptions on **one** NR. Use the pre-op procedure code for review and observation (01B02) on both the NR and PS. Do not write a separate NR for the Facility–Product Based trend indicator. The plant is responsible for correcting every noncompliance on the NR, but FSIS **does** not issue two NRs when only one procedure was conducted.

Pre-Operational Sanitation Workshop

Answer the following:

1. Define the following pre-op sanitation terms.

   a. area

   b. unit

   c. inspection unit

2. How much time is allowed to inspect an IU?

3. How many areas may one inspector cover when performing pre-operational sanitation inspection?

4. What is industry's sanitation responsibility?

5. What is FSIS's role?

6. Where would you record noncompliance identified during a pre-op sanitation procedure?

7. Name the two types of daily SSOP verification (procedure).

8. Name three parts to the review and observation procedure for pre-op sanitation.

9. Define:

   a. U.S. Rejected

   b. U.S. Retained

Noncompliance Record (NR) and Procedure Schedule (PS)

1. Read the following NR.

2. Based on the description of noncompliance, fill in the correct procedure code in Block 8 and select the most appropriate trend indicator in block 9.

3. Document the PS or the blank PS with the correct code and trend indicator.

1. Read the following NR.

2. Based on the description of noncompliance, fill in blocks 6 through 9.

3. Document the PS or blank PS with the correct code and trend indicator.

Part V – SSOP Operational Sanitation – 01C01 and 01C02

The plant is responsible for maintaining sanitary conditions and preventing product adulteration or contamination during operation. Inspectors conducting PBIS procedures for operational sanitation are responsible for verifying the plant's effectiveness.

- Remember to give the plant an opportunity to execute its SSOP. Allow the system to work.

  For example, if you observe a small amount of meat on the floor while conducting operational sanitation inspection, you might first look at the plant's monitoring records. If you determine that the plant's monitoring checks are being done on time, wait for the next scheduled monitoring check to see if the plant employee responsible for the checks notices the meat on the floor and takes corrective action. If he or she monitors at the appointed time, takes corrective actions, and documents the corrective actions, the system is working. Do not

document noncompliance. However, if the responsible employee does not return to monitor the area, does not correct the situation, or does not document the findings and corrective action, there is noncompliance and you should write a NR.

- There are also times when an inspector should not wait for the system to work. If waiting would allow contaminated product to be shipped without being detected, retain product, and write a NR.

  For example, if an inspector observed condensation dripping directly onto product and plant personnel are unaware of the situation, it is obvious the contaminated product will go on down the line and leave the plant undetected. Take immediate action to retain the product. In this situation, an inspector should not wait for the next monitoring check because that would be too late to stop the contaminated product.

Records Review Procedure 01C01

Recordkeeping procedures review the plant's daily documentation of its operational sanitation procedures and any required corrective actions. Inspectors perform this procedure to verify that:

- SSOP procedures are being followed by plant personnel during operations
- Monitoring activities are conducted at the specified frequency
- All 3 requirements of corrective actions are implemented and documented as required
- Plant employees specified in the SSOP initial and date records. When SSOP records are kept on a computer, the plant must implement controls to ensure data integrity.

The inspector should determine if there is any evidence of misrepresentation or falsification of SSOP records.

Review and Observation Procedure (01C02)

The review and observation procedure has three elements.

- Direct observation of the plant's implementation and monitoring of sanitation procedures and required corrective actions.

- Organoleptic examination of a random sample of facilities, utensils, and equipment to assess sanitary conditions.

- A comparison of inspection findings with plant records for the day.

Review and observation may be conducted using some or all the parts. For example, the inspector might choose to observe plant personnel conducting operational monitoring check and determine whether records are being documented correctly.

Documentation

Operational sanitation noncompliance is documented on a NR the same way as pre-operational sanitation inspection.

- Consult the ISP for the applicable regulatory reference for records review procedure (01C01) or the review and observation procedure (01C02).

- Select the most appropriate SSOP trend indicator when noncompliance involves direct product contamination and adulteration.

- Use the Facility code (06D01) when noncompliance does not involve direct product contamination or adulteration.

Facility trend Indicators

Facility–Lighting

FSIS regulations require sufficient light properly conduct inspection. (307.2 (b)). Noncompliance with regulatory lighting requirements is documented under the Facility-Lighting trend indicator. In red meat plants, a minimum of 50 footcandles of shadow-free lighting at the following inspection stations is required.

- Head inspection

- Viscera inspection

- Carcass inspection

Facility –Structural

Use the Facility–Structural trend indicator when walls, floors, beams, etc., are insanitary but do not directly or indirectly contaminate product. The following are examples:

- Flaking, peeling on a wall away from the product
- Flaking, peeling paint on a ceiling or overhead beam not over product
- Holes in the floor
- Condensation not over exposed product

Facility–Outside Premises

Use the Facility–Outside Premises trend indicator when insanitary conditions existing outside the slaughter/processing area do not constitute a direct threat to product contamination. The following are examples.

- Standing water at loading dock
- Tall weeds around the building
- Unused equipment piled up on the ground.

Operational Sanitation Workshop

Answer the following questions.

1. Given the following list, identify those which are in a:

    a. Food contact zone
    b. Non-food contact zone

_____Truck dock for unloading cattle

_____Offal room

_____Moving viscera table

_____Hole in wall behind hide puller

_____Outside area near trash dumpster

_____Cutting boards in boning room

_____Lunchroom

_____Sweetbreads chiller

_____Carcass splitting saw

2. Identify the regulatory action you would take if you found condensation, scaling rust, or peeling paint overhead in a:

   a. food contact zone

   b. non-food contact zone